

Food and Drug Administration, HHS

§ 892.6500

source located at a distance from the patient's body.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 59 FR 63015, Dec. 7, 1994]

§ 892.5750 Radionuclide radiation therapy system.

(a) *Identification*. A radionuclide radiation therapy system is a device intended to permit an operator to administer gamma radiation therapy, with the radiation source located at a distance from the patient's body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts (including beam-limiting devices), and accessories.

(b) *Classification*. Class II.

§ 892.5770 Powered radiation therapy patient support assembly.

(a) *Identification*. A powered radiation therapy patient support assembly is an electrically powered adjustable couch intended to support a patient during radiation therapy.

(b) *Classification*. Class II.

§ 892.5780 Light beam patient position indicator.

(a) *Identification*. A light beam patient position indicator is a device that projects a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam. The beam of light is intended to be used during radiologic procedures to ensure proper positioning of the patient and to monitor alignment of the radiation beam with the patient's anatomy.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

§ 892.5840 Radiation therapy simulation system.

(a) *Identification*. A radiation therapy simulation system is a fluoroscopic or radiographic x-ray system intended for

use in localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field produced. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification*. Class II.

§ 892.5900 X-ray radiation therapy system.

(a) *Identification*. An x-ray radiation therapy system is a device intended to produce and control x-rays used for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification*. Class II.

§ 892.5930 Therapeutic x-ray tube housing assembly.

(a) *Identification*. A therapeutic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing intended for use in radiation therapy. This generic type of device may include high-voltage and filament transformers or other appropriate components when contained in radiation-shielded housing.

(b) *Classification*. Class II.

Subpart G—Miscellaneous Devices

§ 892.6500 Personnel protective shield.

(a) *Identification*. A personnel protective shield is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation. This generic type of device may include articles of clothing, furniture, and movable or stationary structures.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in